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10/069,803	02/25/2001	Bruno Donatini	GEI-089	7157

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	8

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/069,803	Donatini
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 13, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 8, 11, and 13-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 8, 11, and 13-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on February 3, 2003. Acknowledgment is made of Applicant's cancellation of Claims 2-10 and 12, and newly added Claims 15-22.

Claims 1, 8, 11 and 13-22 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 11, and 13-22 as amended are/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 1, lines 1-2, recites "Pharmaceutical dietary composition" without an article before the subject of the claimed invention. It is suggested that Applicant replace the phrase with A pharmaceutical dietary composition to clarify the claimed invention.

Claims 34-36 recite the limitation "derivative". One of ordinary skill in the art would not know how to interpret the metes and bounds of this limitation. A derivation of a chemical compound may be closely patterned after the subject chemical compound or may be loosely patterned after the subject chemical compound, such that it may bear no resemblance or form

recognizable as the subject chemical compound which maybe chemically and/or biologically unrelated in function or form to the subject chemical compound.

With regard to Claim 1, line 3, there is an apparent typographical error. Applicant may overcome the rejection by replacing "selectd" with selected.

Claims 11, 16, 18, 20 and 21 recite the limitation "the chitosan". The claims lack clear antecedent basis for this limitation in the claims.

With regard to Claim 13, line 3, there is an apparent misspelling. Applicant may overcome the rejection by replacing "Agaricus bisorus" with Agaricus bisporus.

With regard to Claim 14, line 3, there is an apparent misspelling. Applicant may overcome the rejection by replacing "suffient" with sufficient.

Claim 17 recites the limitation "the anionically-substituted chitosan derivative" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Regarding Claim 22, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. MPEP § 2173.05(d).

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13 and 16-18 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al.(JP 08-131120, AA3). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant argues Tanaka fails to anticipate the claimed invention because the referenced health food comprises numerous ingredients in addition to chitosan and fungi, is prepared by molding, and "contains only 2 % of chitosan", whereas the claimed composition contains as "the active ingredient a combination of fungi and chitosan having therapeutic properties and being free of contaminates." Applicant further argues that the amount of chitosan contained therein the referenced composition can not chelate contaminates. However, Applicant's arguments are neither persuasive nor commensurate in scope to the claimed limitations because Tanaka teaches a health food noodle composition comprising *Ganoderma lucidum*, powder of fungi, and chitosan lactic acid solution, which is used for cleaning of blood, stimulation of bloodstream, prevention of sleepiness, liver disorders and cancer treatments. On page 2 of the translation, lines 4-5, Tanaka teaches a mixture of *Ganoderma lucidum* and wild-rice powder having cancer inhibiting activity.

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. The prior art is silent on the claimed functional effect of chitosan as a chelating agent and the chitosan having a pH less than 6. However, Tanaka does teach that the composition comprises a chitosan lactic acid solution; and, therefore the claimed pH range of the chitosan comprising the composition taught by Tanaka must be inherent to the referenced composition. Moreover, as the referenced composition comprises the claimed ingredients, the claimed functional properties of the disclosed composition must be inherent to the referenced composition, since the prior art teaches that the composition comprises an edible therapeutic fungi and a chitosan.

The reference anticipates the claimed subject matter.

Claims 1, 8 and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Takenaka et al. (JP 09-149774, AA5). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant's main argument is directed to the idea that Takenaka fails to anticipate the claimed subject matter because the referenced composition contains only 1% of chitosan which is quite different from the percent amount by weight of chitosan comprising the composition claimed by Applicant. However, Applicant's argument is neither persuasive nor commensurate in scope to the limitations of the claims because Takenaka teaches a composition comprising an extract of mushroom, *Agaricus blazei* Murr, and chitosan, which is an anti-oxidation dietary health food product. The mushroom extract is taught as a polysaccharide having immunological enhancing

and cholesterol lowering properties. The composition taught by Takenaka is prepared by admixing an extract of microalga with hot water to chitosan, agar and mushroom extract at a pH of 8.

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. The prior art is silent on the claimed functional effect of chitosan as a chelating agent. However, as the referenced composition comprises the claimed ingredients, the claimed functional property must be inherent to the referenced composition, since the prior art teaches that the composition comprises an edible therapeutic fungi and a chitosan.

The reference anticipates the claimed subject matter.

Claims 1, 3 and 11, 14 and 22 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Kato (JP 08-322506, AA2). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant fails to argue the rejection made under 35 USC 102 with regard to the teachings of Kato. Instead on page 8 of Applicant's response (Paper No. 7), Applicant argues Kato with regard to the meaning of 35 U.S.C. 103. Thus, the subject matter is deemed to anticipate the claimed subject matter because Kato teaches a health food pharmaceutical comprising 60-40 wt. % of the edible mushroom, *Grifola frondosa* (maitake mushrooms), and 40-60 wt. % of chitosan. The *Grifola frondosa* used in the preparation of the composition is preferably a dried product, but may also be used fresh. The composition taught by Kato is used for the treatment of hyperlipemia, weight-loss and for improving immunological function. Kato further teaches the

individual therapeutic effects of *Grifola frondosa* and chitosan. For example. In [0003], Kato teaches that chitosan as a food additive promotes the excretion of chlorine present in food (when it is ingested). In [0015], Kato teaches that the chitosan used in the method of preparing his composition is used mainly as a heavy metal adsorbent and contaminant remover in various industries, such as a cation system (thus, a basic chitosan) activated sludge condensation material or recovery of protein in waste fluid; but, as a biocompatible material, Kato teaches that the chitosan of his invention physiologically removes cholesterol and other impurities from the body (when it is ingested). In [0016], Kato teaches that the edible mushrooms contain numerous elemental nutrients. A method of administering the referenced composition is taught in [0019].

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. Although Kato does not expressly teach the chitosan comprising the referenced composition as a chelating agent, the claimed functional property is inherent to the composition taught by Kato because the ingredients, the amounts of the ingredients, and the beneficial functional health effect of the composition taught by Kato are one and the same as instantly claimed by Applicant.

The reference anticipates the claimed subject matter.

Claims 1, 8, 11, 13, 16 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Onodera et al. (N). Newly applied as necessitated by amendment.

On page 3, lines 4-25, Onodera teaches a composition comprising a solution of dry powdered chitosan-producing microorganism, e.g., *Agaricus bisporus,* in acetic acid. On page 4, line 6 to page 5, lines 1-9, Onodera teaches adding cells of various fungi to acetic acid to extract chitosan, and adding sodium hydroxide solution to adjust the pH of the filtrate to 9.5.

Onodera does not expressly teach the referenced composition as a pharmaceutical dietary composition. However, the ingredients, and the percent weight amount of the chitosan comprising the composition taught by Onodera are one and in the same as instantly claimed by Applicant. Therefore, the beneficial effect of the composition taught by Onodera must be one and the same as instantly claimed by Applicant. It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting: "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best,* 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of

showing that they are not." *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

The reference claims the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3 and 11, 14, 15 and 22 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Kato (JP 08-322506, AA2). Newly applied as necessitated by amendment. Applicant further claims a method according to claim 14 wherein the composition is in the form of cakes or biscuits.

The teachings of Kato are set forth above. Kato does not teach a method for treating obesity, memory disorders of asthma in humans comprising administering to humans in need thereof an amount of the claim-designated composition wherein the composition is in the form of cakes or biscuits. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the form of the health-assisting food composition taught

by Kato by modifying the referenced powdered composition into the form of either cakes or biscuits, based on the beneficial teachings provided by the reference as a whole. For instance, Kato clearly teaches that the health-assisting supplemental food product can be administered before a meal, after a meal, or as a meal in the form of a powder, in [0019]. One of ordinary skill in the art at the time the invention was made would have been motivated and one would have had a reasonable expectation of success to optimize the form of delivery of the composition taught by Kato to provide the claimed invention because Kato clearly teaches that the referenced composition removes cholesterol and other impurities from the body when ingested and contains numerous elemental nutrients. As Kato clearly teaches that the blended powdered form of the referenced composition can be conveniently used as a supplemental food product and is easily consumed before, after or during a meal, one of ordinary skill in the art would have had a reasonable expectation of success at the time the invention was made to optimize the form of delivery of the composition taught by Kato to cakes or biscuits for the purpose of promoting health benefits, such as weight loss in the obese, and the commercialization of such a product. Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to optimize the delivery form of the referenced composition to provide the claimed invention because it would have been well in the purview of one of ordinary skill in the art practicing the invention to select a form of delivery for the administration of a drug that would have beneficial functional effects such as weight loss and convenience.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 3, 11, 13-15, 18 and 19 as amended/are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato (JP 08-322506, AA2) in view of Angerer et al. (A). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

The main idea of Applicant's argument is directed to the idea that Applicant's invention is not related to dietary compositions which may contain vitamins, such as D3. Applicant concedes that Kato clearly teaches a food comprised mainly of enriched chitosan, activated D2, and a polysaccharide extracted from *Grifola frondosa*. Nonetheless, Applicant concludes that the combination of the prior art fails to render the claimed composition obvious.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary reference of Kato was relied upon because for the reasons set forth above and for the reasons set forth in the previous Office action. Because Kato does not teach a pharmaceutical composition further comprising an acid chitosan the secondary reference of Angerer was relied upon because Angerer teaches a water-soluble acid-chitosan complex which is administered to animals for the prevention of fat digestion, in Column 1, lines 9-14. In Column 2,

lines 26-29, Angerer teaches administering the acid-chitosan to reduce the release of triglycerides into the blood stream of animals. See Column 4, line 51 to Column 5, lines 1-36, also. The acid-chitosan is prepared by mixing chitosan and betaine hydrochloride, and has a pH of 3 (see Column 6, lines 1-10).

Thus, with Kato providing the motivation of using a health food pharmaceutical comprising 60-40 wt. % of the edible mushroom, *Grifola frondosa* (maitake mushrooms), and 40-60 wt. % of chitosan for the treatment of hyperlipemia, weight-loss and for improving immunological function; and with Angerer teaching administering a water-soluble acid-chitosan complex to animals for the prevention of fat digestion, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed old and well-known ingredients to provide the claimed invention for use as a therapeutic in the treatment of obesity in humans comprising the administration of the claim-designated composition, as suggested by the cited references. Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention may be predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or

amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference. Therefore, the invention as a whole was clearly prima facie obvious in the absence to the contrary.

Allowable Subject Matter

Claims 20 and 21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

May 1, 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER